JUN 7 - 2005

K050538

10.0 SUMMARY OF THE SAFETY AND EFFECTIVENESS

International Medsurg Connection Surgical Drape

Manufacturer:	International Medsurg Connection, Inc. 935 N Plum Grove Road, Suite F Schaumburg, Illinois 60173-4770
Regulatory Contact:	Manny Gupta Vice President / General Manager International Medsurg Connection, Inc. 935 N Plum Grove Road, Suite F Schaumburg, Illinois 60173-4770
Telephone:	847-619-9929
Date Summary Prepared:	February 18, 2005
Product Trade Name:	Angiography & Cardiovascular Drapes
Common Name:	Surgical Drape.
Classification:	Class II
Predicate:	Surgical Drapes, Reference K030365 owned by DeRoyal Industries.
Description:	International Medsurg Connection Surgical Drape.

Intended Use:
International Medsurg Connection's Surgical Drape is intended to be used as patient protective coverings used to isolate incision sites and protect against contamination during surgical procedures.

Substantial Equivalence:
The International Medsurg Connection Surgical Drapes are substantially equivalent to the DeRoyal Surgical Drape sold by DeRoyal Industries, Reference K030365.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 - 2005

Mr. Manny Gupta
Vice President/General Manager
International Medsurg Connection, Incorporation
935 N. Plum Glove Road, Suite F
Schaumburg, Illinois 60173-4770

Re: K050538
Trade/Device Name: IMC Angiography & Cardiovascular Drapes
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: April 25, 2005
Received: April 28, 2005

Dear Mr. Gupta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510K Number : K050538

Device name: IMC Angiography & Cardiovascular Drapes

Indication For Use:

This device is intended to be used as protective coverings used to isolate incision sites and protect against contamination during surgical procedures.

This submission includes drapes that will be sold both sterile and non-sterile. Non-sterile drapes are to be sold to OEMs for EtO sterilization according to ISO 11135. Sterile drapes are to be sold directly to users after EtO sterilization, validated to ISO 11135.

Prescription Use__X_____ AND/OR Over-The counter Use_____
(Partb21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of anesthesiology, General Hospital.
Infection Control Dental Devices

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050538